Section 4: 510(k) Summary

JUL 25 2014

K133658

This section includes a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Terumo Cardiovascular Systems Corporation
Address	6200 Jackson Road Ann Arbor MI, 48103
Name of Contact Person	John Chesney
Phone number	Tel: (734) 741-6410
Fax number	Fax: (734) 741-6069
E-mail	john.chesney@terumomedical.com
Establishment Registration #	1828100
Date prepared	July 22, 2014
Name of Device	
Trade or proprietary name	CDI™ Blood Parameter Monitoring System 500
Common or usual name	Extracorporeal blood gas monitor
Classification name	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass
Classification panel	74 Cardiovascular
Regulation	21 CFR §870.4330
Product Code(s)	DRY
Legally marketed device(s) to which equivalence is claimed	CDI Blood Parameter Monitoring System 500, K123039 and K972962
Reason for 510(k)	Modifications to previously cleared system

Device Information

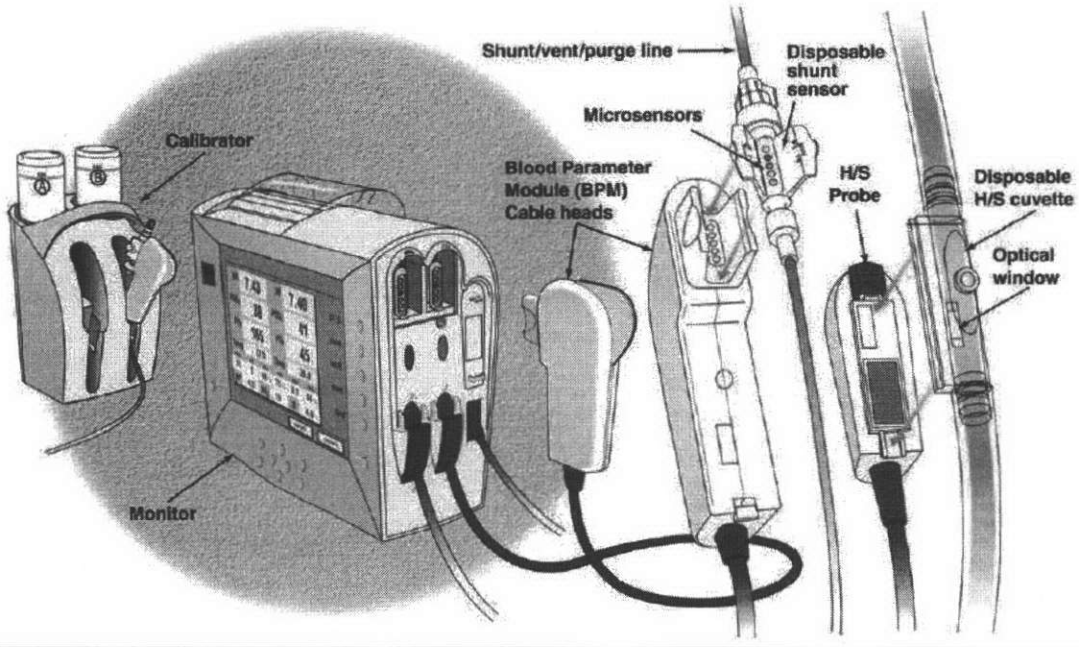
Indication for Use: The CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

Device Description: The CDI™ System 500 is an AC-powered (battery back-up) microprocessor-based device used with the following components/accessories:

- CDI™ 500 Monitor
- Arterial and/or Venous Blood Parameter Modules (BPM)
- CDI™ H/S Probe
- CDI™ 540 Gas Calibrator and Calibration Gases (A and B)
- CDI™ 510H Shunt Sensor
- Shunt Bypass Line
- CDI™ H/S Cuvette with or without extension tubing
- Monitor Mounting Hardware (Pole Clamp and Cable Head Bracket)
- Printer Paper

The CDI™ System 500 measures blood parameters in real time by utilizing a microprocessor based monitor, electro-optics modules (i.e., BPM and H/S probe), fluorescence chemistry technology, and optical reflectance technology. The electro-optics modules connect the monitor to the disposables (i.e., shunt sensor or cuvette) which are inserted into the extracorporeal circuit. Light is emitted from the modules, and the optical responses from the blood via the sensor(s) are measured by the monitor. The blood parameters are measured or calculated by the CDI™ 500 Monitor in real time, and displayed to the user via a graphical LCD display.

Device Illustration:



Substantial Equivalence

The modified CDI™ System 500 is substantially equivalent to the both the cleared CDI™ System 500 of K123039 and K972962, because it has the same intended use, substantially equivalent indications for use, and the same or substantially equivalent operating principles and technical specifications. Predicate K123039 included an epoxy encapsulation to encase the BPM electronics board and seal the electronics from changes in moisture/humidity. The epoxy encapsulation is included in the modified CDI™ System 500 as referenced in the table below; other device attributes have remained unchanged as shown in the following table. The CDI™ System 500 software has been revised to improve system performance; however, there have been no changes to system functions or operating principles.

Item	Proposed Device Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device K123039 CDI™ Blood Parameter Monitoring System 500	Predicate Device K972962 CDI™ Blood Parameter Monitoring System 500
Indication for Use	The CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.	The CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.	The CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

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Item	Proposed Device Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device K123039 CDI™ Blood Parameter Monitoring System 500	Predicate Device K972962 CDI™ Blood Parameter Monitoring System 500
Blood Parameters Monitored (measured or calculated)	Arterial and/or Venous: pH pCO_2 (partial pressure of carbon dioxide) pO_2 (partial pressure of oxygen) K+ (potassium) SO_2 (oxygen saturation) Hct (hematocrit) Hgb (hemoglobin) Temperature BE (base excess) HCO_3 (bicarbonate) VO_2 (oxygen consumption) Blood flow rate (Q)	Arterial and/or Venous: pH pCO_2 (partial pressure of carbon dioxide) pO_2 (partial pressure of oxygen) K+ (potassium) SO_2 (oxygen saturation) Hct (hematocrit) Hgb (hemoglobin) Temperature BE (base excess) HCO_3 (bicarbonate) VO_2 (oxygen consumption) Blood flow rate (Q)	Arterial and/or Venous: pH pCO2 (partial pressure of carbon dioxide) pO_2 (partial pressure of oxygen) K+ (potassium) SO_2 (oxygen saturation) Hct (hematocrit) Hgb (hemoglobin) Temperature BE (base excess) HCO_3 (bicarbonate) VO_2 (oxygen consumption) Blood flow rate (Q)
System Components	• CDI500 Monitor with integral printer • Blood Parameter Module (BPM) Probe - optionally one or two for arterial and/or venous use • Optional H/S Probe for venous use • CDI540 Gas calibrator • Gas A / Gas B canisters • Mounting hardware • Printer paper	• Monitor/control unit with integral printer • Blood parameter module (BPM) probe – optionally one of two for arterial and/or venous use • H/S probe • Gas Calibrator • Gas A / Gas B canisters • Disposable accessories (see below)	• Monitor/control unit with integral printer • Blood parameter module (BPM) probe – optionally one of two for arterial and/or venous use • H/S probe • Gas Calibrator • Gas A / Gas B canisters • Disposable accessories (see below)

Item	Proposed Device Modified CDI™ Blood Parameter Monitoring System 500	Predicate Device K123039 CDI™ Blood Parameter Monitoring System 500	Predicate Device K972962 CDI™ Blood Parameter Monitoring System 500
	• Disposable accessories (see below)		
Disposable Accessories	CDI510H Shunt Sensor (for arterial and venous use) with heparin coating Shunt Bypass Line ¼", 3/8", and ½" sizes 18" male/female extension line H/S Cuvettes, with or without 6" extension tube ¼", 3/8", and ½" sizes	CDI510H Shunt Sensor (for arterial and venous use) with heparin coating Shunt Bypass Line ¼", 3/8", and ½" sizes 18" male/female extension line H/S Cuvettes, with or without 6" extension tube (cuvettes with heparin coating no longer available) ¼", 3/8", and ½" sizes	CDI510H Shunt Sensor (for arterial and venous use) with heparin coating In-line Sensor and In-line Cell, ¼", 3/8", and ½" sizes H/S Cuvettes, with or without 6" extension tube, with or without heparin coating ¼", 3/8", and ½" sizes
Blood Parameter Module Cable-Head (BPM)	Epoxy encapsulation	Epoxy encapsulation	No epoxy encapsulation

Performance Testing

The following safety and performance testing was conducted to verify/validate the changes to the CDI™ System 500:

- Software verification and validation testing
- System verification testing in a blood loop to simulate clinical use

Conclusion

The modified CDI™ System 500 is substantially equivalent to the currently marketed CDI™ System 500 because it has the same intended use and substantially equivalent performance specifications as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

July 25, 2014

Terumo Cardiovascular Systems Corp.
John Chesney
6200 Jackson Rd.
Ann Arbor, MI 48103 US

Re: K133658
Trade/Device Name: CDI Blood Parameter Monitoring System 500
Regulation Number: 21 CFR 870.4330
Regulation Name: Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DRY
Dated: June 23, 2014
Received: June 24, 2014

Dear Mr. Chesney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133658

Device Name
CDI™ Blood Parameter Monitoring System 500

Indications for Use *(Describe)*
The CDI™ System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37°C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ken Skodacek for
Bram Zuckerman

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